REMARKS

The Office Action dated February 11, 2003, has been carefully considered. Claims 1-29 are pending in the present application. Claims 1, 12, and 23 have been amended to recite that the sidewall structure is prefabricated. Support for the amendments to claims 1, 12, and 23 can be found in the specification at, for example, page 3, lines 32-33; page 7, lines 1-4; page 10, line 9; and Figs. 1A and 2A. Claim 13 had been amended to correct a typographical error. No new matter has been introduced. Reconsideration of the present application and entry of the above amendments in view of the following remarks are respectfully requested.

I. INFORMATION DISCLOSURE STATEMENT

Pursuant to 37 C.F.R. § 1.98(b), Applicants submit herewith an Information Disclosure Statement; List of References Cited By Applicants; and References AA-FE.

II. CLAIM OBJECTIONS

The Examiner has objected to claim 13 under 37 C.F.R. § 1.75 as being a substantial duplicate of claim 2. Claim 13 has been amended to depend from claim 12. It is believed that this amendment obviates this objection.

III. CLAIM REJECTION UNDER 35 U.S.C. § 102(e)

Claims 1, 3, 8,10-12, 19, 21, and 22 have been rejected under 35 U.S.C. § 102(e) as allegedly being anticipated by U.S. Patent No. 5,545,208 to Wolff *et al.* ("Wolff"). This rejection is respectfully traversed.

Independent claims 1 and 12 are directed to an expandable stent for implantation in a patient comprising a tubular metal body having open ends and a sidewall structure having openings therein, wherein the sidewall structure is prefabricated. A coating is disposed on a surface of the prefabricated sidewall structure, wherein the coating comprises a hydrophobic biostable elastomeric material and a biologically active material. Claim 1 also recites that the coating continuously conforms to the structure in a manner that preserves the openings. Claim 12 also recites that the openings are substantially free of webbing. Claims 3, 8, 10, and 11 depend from claim 1, and thus also include all the limitations recited in claim 1. Claims 19, 21, and 22 depend from claim 12, and thus also include all the limitations recited

braid of fine single or polyfilament metal wire." Specification, page 3, lines 32-33. In addition, "[t]he coating process enables the material to adherently conform to and cover the entire surface of the filaments of the open structure of the stent in a manner such that the open lattice nature of the structure of the braid or other pattern is preserved, in the coated device." Specification, page 4, lines 18-21.

Wolff does not disclose or suggest a sidewall structure that is prefabricated and a coating comprising a hydrophobic biostable elastomeric material and a biologically active material that is disposed on the surface of the prefabricated sidewall structure.

In contrast, Wolff discloses a stent that includes drug eluting filaments that are braided together to form a stent. Col. 7, lines 7-23. The "filaments could be impregnated with a drug and biodegradably elute." Col. 7, lines 20-21. A single filament could be braided into the stent or varying numbers of strands that are drug-eluting could be braided into a filament that forms the stent. Col. 7, lines 7-23. Thus, in Wolff the filaments include a drug or are coated with a drug before the filaments are woven together. Wolff discloses that "[i]n all cases, the prostheses of [Wolff's] invention require the presence of an elutable drug compounded to the prosthesis itself." Col. 2, lines 12-14. (Emphasis added). Thus, the drug coating is not applied to a prefabricated stent, but to the filaments themselves before the filaments are formed into a stent.

Wolff discloses that "[w]ith conventional metal stents, the invention requires a drug-carrying coating overlying at least a portion of the metal." Col. 2, line 14-16. However, as explained above, Wolff does not disclose or suggest that the coating is disposed on a prefabricated sidewall structure of a metal stent. Instead, Wolff discloses a coating on individual filaments that are then woven together. Wolff discloses that the "exterior surface of the metal filaments 22 would include a coating 14 with a drug-eluting polymer." Col. 6, lines 60-61. Wolff also states that Fig. 13 shows a filament that is formed with a metal core 16 and a coating 14. Col. 7, lines 33-34. But Wolff does not disclose or suggest that the filaments are formed into a sidewall structure and then coated with a biologically active material and a polymer. In fact, Wolff teaches away from a coating on a prefabricated sidewall structure by disclosing individual filaments that are coated and then braided or woven or bonded together. Col. 7, lines 7-36.

The Examiner refers to column 9, lines 33-34 which describes Figure 3B of Wolff. Wolff at col. 9, lines 23-25 expressly states that Figure 3B shows that "the *filament* 12 may be made from one or several layers of polymer." (Emphasis added). Wolff does not even use the term "coating" in discussing Figure 3B. Hence, this figure does not show a coating for

the prosthesis but a filament or wire-like portion of the prosthesis itself, *i.e.*, a substrate upon which a coating can be placed. Accordingly, items 14 and 15 shown in Figure 3B are *not* layers of a coating but are instead layers of the filament or prosthesis. Hence, instead of comprising a coating of the prosthesis, items 14 and 15 in Figure 3B comprise the prosthesis itself. In contrast, Applicants' invention is directed to a stent having a prefabricated sidewall structure that is covered by a coating of a hydrophobic biostable elastomeric material and a biologically active material.

Accordingly, Wolff does not disclose or suggest a prefabricated sidewall structure, or a coating that includes a hydrophobic biostable elastomeric material and a biologically active material that is disposed on a prefabricated sidewall structure as required by the present claims. Thus, it is believed that claims 1, 3, 8, 10-12, 19, and 21-22 are patentable over Wolff.

IV. CLAIM REJECTIONS UNDER 35 U.S.C. § 103(a)

A. Claims 2, 4, 5, 13, And 15-16 Are Patentable Over Wolff In View Of U.S. Patent No. 5,900,246 To Lambert ("Lambert")

Claims 2, 4, 5, 13, and 15-16 have been rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Wolff in view of Lambert. This rejection is respectfully traversed.

Claims 2, 4, and 5 depend from claim 1 which was shown above to be patentable over Wolff. Claims 13, 15, and 16 depend from claim 12 which was also shown above to be patentable over Wolff. As acknowledged by the Examiner, Wolff does not disclose or suggest a thickness of a coating as recited in claims 2, 5, 13, and 16. In addition, with respect to claims 4 and 15, Wolff does not disclose or suggest a coating that is applied to the surface of the sidewall structure by spraying. As explained above, Wolff does not even disclose or suggest a coating on a prefabricated sidewall structure. Thus, for these additional reasons, it is believed that claims 2, 4, 5, 13, and 15-16 are patentable over Wolff.

Lambert does not remedy the deficiencies of Wolff. Lambert discloses a stent coated with a polyurethane having a drug incorporated therein. In its examples, Lambert uses nitinol stents or stainless steel coils. However, Lambert does not teach an expandable stent or a stent having a sidewall structure having openings therein. Since Lambert does not disclose or suggest a sidewall structure having openings therein, Lambert fails to disclose or suggest a coated stent having a coating that continuously conforms to the structure in a manner that

coated stent having a coating that continuously conforms to the structure in a manner that preserves the openings or a coated stent having openings substantially free of webbing as recited in the present claims.

Thus, both Wolff and Lambert do not disclose or suggest a prefabricated sidewall structure having openings therein. Moreover, there is no motivation to combine the teachings of Wolff and Lambert where Wolff teaches away from coating a prefabricated sidewall structure having openings therein, and Lambert does not even disclose or suggest a sidewall structure having openings therein.

Accordingly, it is believed that claims 2, 4, 5, 13, 15, and 16 are patentable over Wolff in view of Lambert.

B. Claims 6, 7, 9, 17-18, and 20 Are Patentable Over Wolff In View Of U.S. Patent No. 5,464,650 to Berg *et al.* ("Berg")

Claims 6, 7, 9, 17-18, and 20 have been rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Wolff in view of Berg. This rejection is respectfully traversed.

Claims 6, 7 and 9 depend from claim 1, and claims 17, 18, and 20 depend from claim 12. Claims 1 and 12 were shown above to be patentable over Wolff, and thus the dependent claims are also believed to be patentable over Wolff. With respect to claims 6, 7, 17, and 18, Wolff does not disclose or suggest applying a coating to a stent or a prefabricated sidewall structure as discussed above. In addition, Wolff does not disclose or suggest the metals recited in claims 9 and 20. Thus, it is believed that claims 6, 7, 9, 17, 18, and 20 are patentable over Wolff for these additional reasons.

Berg does not remedy the deficiencies of Wolff. Unlike the present invention, Berg does not describe or suggest a coated stent having openings therein, wherein the coating continuously conforms to the structure in a manner that preserves the openings or wherein the openings are substantially free of webbing as recited in the present claims. Berg is completely silent as to whether the openings in its stent contains a webbing of coating material.

Furthermore, one of ordinary skill in the art would not be motivated to combine Berg with Wolff where Wolff teaches away from coating a pre-fabricated sidewall.

Accordingly, it is believed that claims 6, 7, 9, 17-18, and 20 are patentable over Wolff in view of Berg.

C. Claims 23 And 26-28 Are Patentable Over Lambert

Claims 23 and 26-28 have been rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Lambert. This rejection is respectfully traversed.

Claim 23 recites a "self-expandable stent for implantation in a patient comprising a tubular metal body having open ends and a sidewall structure having openings therein and a coating . . . on a surface of said sidewall structure, . . . wherein said coating continuously conforms to said structure in a manner that preserves said openings." Claims 26-28 depend from claim 23 and thus also include those elements.

As discussed above, Lambert does not disclose or suggest an expandable stent or a stent having a sidewall structure having openings therein. Since Lambert does not disclose or suggest a sidewall structure having openings therein, Lambert fails to disclose or suggest a coated stent having a coating that continuously conforms to the structure in a manner that preserves the openings as recited in the present claims.

Thus, it is believed that claims 23 and 26-28 are patentable over Lambert.

D. Claims 24, 25, And 29 Are Patentable Over Lambert In View Of Wolff

Claims 24, 25, and 29 have been rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Lambert in view Wolff. This rejection is respectfully traversed.

Claims 24, 25, and 29 depend from claim 23 which was shown above to be patentable over Lambert. Lambert does not disclose or suggest an expandable stent or a stent having a sidewall structure having openings therein. Lambert also fails to disclose or suggest a coated stent having a coating that continuously conforms to the structure in a manner that preserves the openings as recited in the present claims. In addition, Lambert does not disclose or suggest more than one coating layer as recited in claim 29.

Wolff does not remedy the deficiencies of Lambert. As discussed above, Wolff does not disclose or suggest a prefabricated sidewall structure or a coating on the surface of such prefabricated sidewall structure. Thus, Wolff also does not disclose or suggest a coating having a particular thickness or a coating that continuously conforms to the structure in a manner that preserves the openings as recited in the present claims. Moreover, one of ordinary skill in the art would not be motivated to combine the teachings of Wolff with Lambert to obtain the present invention.

The Examiner has stated that Wolff teaches that "there can be several polymer coating layers on the stent" and refers to Col. 9, lines 23-24 of Wolff. However, Wolff at col. 9, lines

23-25 expressly states that Figure 3B shows that "the *filament* 12 may be made from one or several layers of polymer." (Emphasis added). Wolff does not even use the term "coating" in discussing Figure 3B. Hence, this figure does not show a coating for the prosthesis but a filament or wire-like portion of the prosthesis itself, *i.e.*, a substrate upon which a coating can be placed. Accordingly, items 14 and 15 shown in Figure 3B are *not* layers of a coating but are instead layers of the filament or prosthesis. Hence, instead of comprising a coating of the prosthesis, items 14 and 15 in Figure 3B comprise the prosthesis itself. In contrast, Applicants' invention is directed to a stent having a prefabricated sidewall structure that is covered by a coating of a hydrophobic biostable elastomeric material and a biologically active material.

Thus, it is believed that claims 24, 25, and 29 are patentable over Lambert in view of Wolff.

E. Claim 14

Claim 14 has not been rejected or objected to by the Examiner. It is respectfully submitted that claim 14 is patentable over the references cited in the Office Action for the reasons stated above.

V. CONCLUSION

As all rejections are believed to be overcome, all claims are believed to be in condition for allowance. An early notice to that effect would be appreciated. Should the Examiner not agree with Applicants' position, then a personal or telephonic interview is respectfully requested to discuss any remaining issues and expedite the eventual allowance of the application.

Respectfully submitted,

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Enclosures